

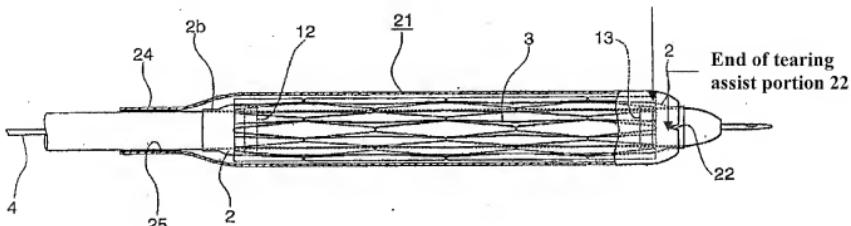
REMARKS

This Amendment is submitted in response to the final Office Action mailed on March 25, 2010. A Request for Continued Examination ("RCE") (\$810.00) is submitted herewith. The Director is authorized to charge \$810.00 for the RCE and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3717424-00015 on the account statement.

Claims 1-13 are pending in this application. In the Office Action, Claim 13 is rejected under 35 U.S.C. §112. Claims 1-13 are rejected under 35 U.S.C. §103. In response, Claim 1 has been amended. The amendment does not add new matter. At least in view of the amendment and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

In the Office Action, Claim 13 is rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. The Patent Office asserts that the Specification fails to provide support for the limitation that "the stent for the vessel is not exposed by the tearing assisting portion." See, Office Action, page 2, lines 10-12. In response, Applicant respectfully notes that the Specification states: "[t]he stent for the vessel 3, mounted on the balloon 2, . . . is covered up with a stent holding member 21." See, Specification, page 5, paragraph 70. The Specification further describes that "the tearing assisting portion 22 needs only to guide the tearing . . . such that it is sufficient only to provided an only small slit in a portion of the stent holding member 21." See, Specification, page 5, paragraph 77. In addition, Figure 9 clearly shows that the end of tearing assist portion 22 does not extend to the beginning of stent 3 and thus covers or does not expose the stent 3.

Beginning of stent 3



See, Specification, Fig. 9. As such, Applicant respectfully submits that the original disclosure clearly supports the limitation that the stent is not exposed by the tearing assist portion.

Accordingly, Applicant respectfully requests that the rejection of Claim 13 under 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 1-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,899,727 B2 to Armstrong et al. ("*Armstrong*") in view of U.S. Patent No. 5,591,222 to Susawa et al. ("*Susawa*"), and further in view of U.S. Patent Publication No. 2004/0010265 A1 to Karpel ("*Karpel*"). In response, Applicant has amended independent Claim 1. In view of the amendment and/or for at least the reasons set forth below, Applicant respectfully submits that, even if combinable, the cited references fail to disclose or suggest each and every element of independent Claim 1 and Claims 2-13 that depend therefrom.

Currently amended independent Claim 1 recites, in part, a device for delivery of a stent for a vessel comprising: a catheter for insertion into the vessel of a living body; a balloon mounted on an outer peripheral surface of a distal end side of said catheter and inflatable with a fluid supplied to said catheter; a stent for the vessel mounted on said balloon in a diameter-contracted state, said stent being formed of a biodegradable polymer and having self-expanding properties; and a stent holding member formed of a polymer material to a tube form for holding said stent for the vessel on said balloon, and configured for covering at least a portion of said stent for the vessel from said catheter; said stent holding member having been drawn in a longitudinal direction and being provided with a tearing assisting portion at a distal end thereof located towards the distal end of said catheter, wherein the polymer material of the stent holding member includes polymer molecules oriented in the longitudinal direction, and wherein the distal end of the stent holding member is contracted in diameter. This amendment does not add new matter. The amendment is supported in the Specification at, for example, page 3, paragraph 31; page 5, paragraph 80; Fig. 9. By providing the stent delivery device such that the distal end of the stent holding member is contracted in diameter, facilitated insertion of the stent into the body may be assured. See, Specification, page 5, paragraph 80. In contrast, even if combinable, the cited references fail to disclose every element of the present claims.

For example, even if combinable, *Armstrong*, *Susawa* and *Karpel* fail to disclose or suggest a stent delivery device, wherein the distal end of the stent holding member is contracted in diameter as required, in part, by independent Claim 1. The Patent Office asserts that *Armstrong* discloses a stent holding member covering the stent for the vessel and having a tearing assist portion provided at a distal end thereof. See, Office Action, page 3, lines 1-13.

The Patent Office further asserts that *Armstrong* teaches a stent holding member covering up the entire length of the stent and that it would have been obvious to make the stent cover longer. See, Office Action, page 6, lines 1-2; page 8, lines 1-4.

However, the portions of *Armstrong* relied on by the Patent Office merely disclose a constraining sheath having a tubular shape and perforations and covering a stent. See, *Armstrong*, column 3, lines 3-13; column 6, lines 26-50; column 8, lines 9-15 and 32-52; column 11, lines 56-62; column 13, lines 23-31; Figs. 1-2B, 3A-3B, 5A and 6A-12C. Although *Armstrong* discusses the smaller insertion diameters of its endoprosthesis and deflated catheter balloon, nowhere does *Armstrong* teach or even suggest its tubular sheath has a smaller diameter at one end thereof. See, *Armstrong*, column 6, lines 10-16, 31-35, 42-48 and 66-67; column 7, lines 1-3 and 9-14; column 9, lines 27-36; column 10, lines 60-67; column 11, lines 1-7, 23-25 and 37-40; column 12, lines 40-42 and 61-64. Instead, *Armstrong* merely teaches that its constraining tube has a single, constant inside diameter. See, *Armstrong*, column 11, lines 56-62; column 12, lines 1-9; column 13, lines 35-60. As such, *Armstrong* fails to disclose that the distal end of its constraining sheath is contracted in diameter.

The Patent Office relies on *Susawa* merely for the disclosure of a stent formed of a biodegradable polymer. See, Office Action, page 4, lines 5-21; page 6, lines 11-22. Similarly, the Patent Office relies on *Karpiel* merely for the disclosure of a stent holding member having vee-slits and being formed of molecules oriented in the longitudinal direction. See, Office Action, page 3, lines 14-21; page 4, lines 1-4; page 5, lines 4-10. Nowhere do *Susawa* or *Karpiel* teach or suggest a stent holding member having a distal end contracted in diameter, nor does the Patent Office cite support for such claimed element. Thus, even if combinable, the cited references fail to disclose a stent delivery device, wherein the distal end of the stent holding member is contracted in diameter as required, in part, by the present claims.

Moreover, one of ordinary skill in the art would have no reason to contract the diameter at the distal end of the stent holding member of *Armstrong* to arrive at the present claims because *Armstrong* fails to teach that the diameter of its stent holding member at the distal end thereof has any particular effect on the performance of its stent delivery device. “A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” See, M.P.E.P. § 2144.05(B) (2009).

Armstrong is entirely directed to a tubular constraining sheath having perforations which are torn upon inflation of a catheter balloon in order to allow the stent to spontaneously deploy. See, *Armstrong*, column 2, lines 66-67; column 3, lines 1-26. *Armstrong* teaches that the proximal end of its sheath may be affixed to the catheter 16 by extension strands 61 in order to facilitate removal of the sheath after the stent is deployed. See, *Armstrong*, column 7, lines 62-67; column 8, lines 1-8; Fig. 6A. However, nowhere does *Armstrong* disclose constraining the diameter of its sheath at the distal end, nor that the diameter of its constraining sheath at the distal end achieves any particular result. Thus, Applicant respectfully submits that one skilled in the art would have no reason to modify or optimize the diameter of the stent holding member of *Armstrong* at a distal end thereof in order to obtain a stent delivery device, wherein the distal end of the stent holding member is contracted in diameter in accordance with the present claims.

Accordingly, Applicant respectfully requests that the rejection of Claims 1-13 under 35 U.S.C. §103(a) to *Armstrong*, *Susawa* and *Karpel* be withdrawn.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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